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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,990	01/17/2005	Abraham Loyter	73236/JPW/GJG/MJW	9138

7590 05/02/2007
John P. White
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1185 Avenue of the Americas
New York, NY 10036

EXAMINER

SNYDER, STUART

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,990	Applicant(s) LOYTER ET AL.	
	Examiner Stuart W. Snyder	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-50 is/are pending in the application.
- 4a) Of the above claim(s) 36-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-35 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/1/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and species related to antibodies, variants or fragments thereof in the reply filed on 2/23/2007 is acknowledged. The traversal is on the ground(s) that:

- A. The claims have a common inventive concept in compliance with PCT Rule 13.1. Applicants assert that they were the "first to identify and disclose the substance that specifically binds at least one of...the [NLS] of Vpr...or...the HIV-1 protein Tat...".
- B. The subject matter is share amongst all of the claims.

This is not found persuasive because:

- A. The common technical feature of the claimed inventions is the ability of the substance to bind to a nuclear localization signal (NLS) of either tat- or vpr-encoded proteins. This is not a special technical feature because others have purified or synthesized molecules that bind NLS of various viruses or oncogenes. Contrary to applicants' assertion of priority, several other investigators have developed "substances"—antibodies—that bind to the NLS of Vpr and Tat (see, for example, Levy, et al. (1994) and Brake, et al. (1990)). Thus binding to an NLS of Tat or Vpr is not a "Special Technical Feature" conferring Unity of Invention and restriction is proper. Applicant has not provided specific arguments disputing the aforementioned facts.

B. The subject matter of 42-50 do not contain all of the limitations of claims

27-41. For example, claims 42-45 specifically recite claims 27, 29 and 30.

Explicitly absent from this recitation is the elected species of claim 33; claims 42-45 read on substances that bind the named NLSs but do not limit the method to only antibody-like substances or derivatives thereof.

In view of the facts presented above, applicants' arguments are not compelling. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 27-35, as they read on antibody-like molecules, are subject of the instant examination; claims 36-50 are currently withdrawn from examination as pertaining to non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 27-33, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a judicial exception to 35 U.S.C. 101 (*i.e.*, a natural phenomenon) and is not directed to a practical application of such judicial exception (*e.g.*, because the claims do not require any physical transformation). The claims read on, *inter alia*, antibodies that arise from inoculation of mice with vpr or tat or from the natural course of infection of humans with HIV or other proteins that bind to Vpr or Tat during the natural replicative cycle of the virus especially those proteins involved in nuclear transport and/or integration of proviral DNA. Thus, the claims read on natural phenomenon

that are devoid of the "hand of man" and are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-28, 30, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy, et al. Claims 27-28, 30, and 33 are drawn to substances that bind, inter alia, the NLS of HIV-1 vpr, specifically including naturally occurring antibodies. Levy, et al. teaches production of such antibodies in rabbits by immunization with recombinant Vpr and followed by boosting with Vpr-derived peptides; the peptides are contained one of two putative Vpr NLS domains—aa 1-71 and 73-96 (according to Jenkins, et al. (1998)). Thus, Levy, et al. teaches all of the limitations of claims 27-28, 30 and 33 and anticipates these claims.
5. Claims 27-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Brake, et al. Claims 27-29 and 31-33 are drawn to substances that bind, inter alia, the NLS of HIV-1 tat, specifically including naturally occurring antibodies. Brake, et al. teaches production of such antibodies in mice and MAb derived therefrom immunization with peptides within the HIV-1 tat NLS, as taught by Levy, et al. and the specification of the instant application. Thus, Brake, et al. teaches all of the limitations of claims 27-29 and 31-33 and anticipates these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins, et al. and Brake, et al. as applied to claims 27-33 above, and further in view of Parmley and Smith (1988) and Winter, et al. (1994). Jenkins, et al. and Brake, et al. teach substances that bind to Vpr and Tat, respectively. Jenkins, et al. and Brake, et al. do not teach scFv or recombinant scFv. Parmley and Smith (1988) and Winter, et al. (1994) teach production of scFv and recombinant scFv using phage display technology—Parmley and Smith were the inventors of the technique. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of Jenkins, et al. and Brake, et al. by using phage display techniques as taught by Parmley and Smith (1988) and Winter, et al. (1994). The skilled artisan would have been motivated to do so because of the ease

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and rapidity of phage display technology, as taught by Parmley and Smith (1988) and Winter, et al. (1994). There would have been a reasonable expectation of success, given general applicability of the method, as taught by Winter, et al. (1994). Thus, the invention of claims 34-35 was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim Objections

7. Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 is drawn to a substance that is a scFv. Claim 35 recites "wherein said scFv is a recombinant scFv" in an attempt to further narrow the scope of claim 34. However, by definition and as described in Applicants' specification, all scFvs are recombinant. Therefore, claim 35 does not limit the subject matter of claim 34.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS

A handwritten signature in cursive script that reads "Bruce Campell".

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600